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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/895,913	06/29/2001	Harold Kleanthous	06132/043002	3260

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EXAMINER
PORTNER, VIRGINIA ALLEN

ART UNIT	PAPER NUMBER
1645	8

DATE MAILED: 07/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/895,913	Kleanthous et al
Examiner	**Art Unit**
Portner	1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jun 29, 2001* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under ***Ex parte Quayle***, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-38* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 1-38 are pending.

Sequence Compliance

1. The instant specification is now in sequence compliance.

Election/Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7, and 30-37 are, drawn to isolated nucleic acid molecules, vectors, host cells, and a method of using said host cells to produce a polypeptide, classified in class 536, subclass 23.1.

II. Claims 27-29 are, drawn to a method of treating a subject for H. pylori infection, classified in class 514, subclass 44.

III. Claim 38 is, drawn to a method of treating Helicobacter infection with antibodies, classified in class 424, subclass 150.1.

IV. Claims 8-10, and 23-26 are, drawn to various polypeptides, classified in class 530, subclass 350.

V. Claims 11-22, drawn to methods of treating a subject for infection, classified in class 530, subclass 387.1.

3. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

4. The inventions are distinct, each from the other because of the following reasons:

5. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product, specifically the isolated nucleic acid molecules, vectors and host cells may be used in methods of making a recombinantly produced polypeptide, wherein the purified nucleic acids may be in turn be useful in methods of treating, generating a vaccine or detecting infection .

6. The invention of group I is distinct from the invention of group IV because it is drawn to materially different compositions that require non-coextensive areas of search and consideration. For example, the proteins of the invention of Group IV may be isolated from natural sources and are not necessarily defined by the DNAs that encode them.

7. Inventions IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product

as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product , specifically in methods of detecting antibodies, in methods of purifying antibodies, as well as in methods of generating a vaccine .

8. Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, functions, and effects. In addition to the preceding restriction requirement, upon the election of Group I, the following additional election would be required:

In addition to the above Restriction the following Election is also required:

9. **Group I**, claims 1-7 and 30-37 are drawn to a plurality of disclosed patentably distinct products comprising materially different polynucleotides. Should the inventions of Group I be elected, Applicant would be required under 35 U.S.C. 121 to elect a single disclosed product, even though this requirement is traversed. The separate polynucleotides bear no structural or biochemical property in common and therefore encode distinct protein products and would require a separate area of search and consideration tailored to the particular product under consideration.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

10. **Group II**, claims 27-29 are, drawn to a plurality of patentably distinct method of treating a subject for H. pylori infection, using the polynucleotides of Group I. Should the inventions of Group II be elected, Applicant would be required under 35 U.S.C. 121 to elect a single disclosed product, of Group I, to be used in the method of Group II, even though this requirement is traversed. The separate polynucleotides bear no structural or biochemical property in common and therefore encode distinct protein products and would require a separate area of search and consideration tailored to the particular product under consideration.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. **Group IV**, claims 8-10 and 23-26 are drawn to a plurality of disclosed patentably distinct products comprising materially different polypeptides/proteins. Should the inventions of Group IV be elected, Applicant would be required under 35 U.S.C. 121 to elect a single disclosed product, even though this requirement is traversed. The separate proteins bear no structural or biochemical property in common and therefore each particular protein product claimed and would require a separate area of search and consideration tailored to the particular product under consideration.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

11. **Group III**, claim 38 is, drawn to a plurality of patentably distinct methods of treating Helicobacter infection with antibodies, wherein the antibodies are induced by using the polypeptide of Group IV. Should the inventions of Group III be elected, Applicant would be required under 35 U.S.C. 121 to elect a single disclosed product, of Group IV to which the antibodies would be induced and used in the method of treating even though this requirement is traversed. The separate proteins bear no structural or biochemical property in common and

therefore each antibody product would evidence distinct binding characteristics and would require a separate area of search and consideration tailored to the particular product under consideration.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

12. **Group V**, claims 11-22, are drawn to plurality of patentably distinct methods of treating a subject for infection, using the polypeptide of Group IV. Should the inventions of Group V be elected, Applicant would be required under 35 U.S.C. 121 to elect a single disclosed product, of Group IV to be used in the method of treating even though this requirement is traversed. The separate proteins bear no structural or biochemical property in common and therefore each particular protein product claimed and would require a separate area of search and consideration tailored to the particular product under consideration.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

13. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their different classification, recognized divergent subject matter, and because the searches required for the separate groups of inventions are non-coextensive, restriction for examination purposes as indicated is proper.

14. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this group is (703) 308-4242.

The Group and/or Art Unit location of your application in the PTO will be Group Art Unit 1645. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to this Art Unit.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vgp
July 24, 2002

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600